

OUTLINE OF A DEPOSITION
WITH THE FEDERAL TRADE COMMISSION

I. INTRODUCTION

The recent proposal that the cigaret industry show FTC "tar" and nicotine deliveries on cigaret packages and in cigaret advertising is based on a number of assumptions regarding smoking and health which are subject to serious question. If these assumptions cannot be supported in fact, or are open to substantial doubt by a body of expert opinion, the Federal Trade Commission may be severely criticized for its lack of objectivity in imposing on the public false and misleading information. It is the purpose of this deposition to point out these potential pitfalls to the Commission before action is taken in this matter.

II. Historical Basis for Emphasis on "Tar"

The broad basic assumption here is that smoking more cigarets means more pathology and that, therefore, more "FTC tar" also means more pathology.

A. Epidemiological Basis

1. Data associating cigaret smoking and health are based on the smoker's own estimate of his cigaret consumption

i. These data are unreliable for the following reasons:

- a. The populations studied are not representative of the total population - morbidity and mortality experience of the populations studied do not agree with the total population experience.
- b. The association between cigaret utilization and pathology is the basis for the hypothesis or assumption that cigaret smoking causes disease, and that nothing else is involved.

ii. The smoker's estimate of his cigaret consumption has been found to be an unreliable estimate.

- a. It is not reliable in its own right
- b. It is not related to his actual intake into the mouth
- c. It is not related to what he takes into his lungs. This may explain the fact that the vast majority of smokers do not get

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the so-called associated diseases.

- B. The term Smoke "Tar" has gained significance because of the early test which purported to show that the biologically active agent as defined in the mouse skin painting test was found in the condensable fraction of the smoke.
1. Review of the early bioassays
 2. Definitions of terms which illustrate the lack of relationship between the smoke condensate "tar" used in the skin painting test and the whole smoke obtained by the smoker from the cigaret.
 - a. Total particulate matter "tar"
 - b. "Gas phase smoke" - that part coming through the Cambridge filter
 - c. FTC "tar"
 - d. Whole smoke condensate "tar"
 - e. Skin painting "tar"

CONCLUSION - There is very clear evidence from the chemistry of smoke that smoke as taken in by the smoker is appreciably different in composition from the smoke "tar" fraction being filtered out in the Cambridge filter which, in turn, is different in composition from the smoke being condensed to produce the "tar" for the broadly accepted mouse skin painting test. If we hypothesize that disease is caused by chemicals in smoke, we might equally validly hypothesize that differences in smoke composition must give rise to differences in biological effects.

- C. The relevance of mouse skin painting test.

Skin tests are used to test the carcinogenicity of many substances. It has been the technique for several decades to determine the carcinogenetic potential of different whole smoke condensates. The obvious question this technique raises is the extrapolation from this to human beings.

There are obvious differences: (a) mice and human beings are different animals; (b) mouse skin is not a human lung; (c) skin painting is not inhalation; (d) the whole smoke condensate is not whole smoke. With these four obvious differences in mind, is the analogy of skin cancer in a mouse painted with smoke condensate and the squamous cell carcinoma in a human being who is smoking a cigaret a valid one?

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III. Differences in activities of "tars" produced in the same manner showing that from different sources and prepared in different ways they are not the same.

- A. The biologic activity of "tar" has decreased over the past 15 years. Wynder & Hoffman (1968) have cited their own work which demonstrates that from the year 1955 to 1965 cigaret condensate, mg for mg, has reduced biological activity. Mice yielded fewer tumors at the end of the period than at the beginning. The drop was from ~45% to ~20%. To show that the susceptibility of mice had not decreased over that period and that the technique for producing tumors in mice had not changed, the numbers of tumors produced by painting with BaP had increased during the same time period from ~65% to ~80%.
- B. "Tar" derived from burley tobacco is less active, biologically, than "tar" from bright tobacco. Wynder & Hoffman (1965) showed that mg for mg different tobaccos gave different % mice showing papillomas: bright and Turkish gave ~35%, while Maryland gave ~25% and burley only ~18%.
- C. Air-cured tobacco gives a "tar" which has less biologic activity than flue-cured tobacco. Bock, Moore & Clark (1965) demonstrated that condensate from English cigaretts (flue-cured) gave tumors on ~45% of the mice while American cigaretts (a blend of air-cured and flue-cured) produced tumors on only ~20% of the mice.
- D. "Tar" derived from cigars is more active than "tar" from cigarettes. Davies & Day (1969) showed that ~28% of mice painted with condensate of a standard British cigaret had tumors while ~45% of mice painted with condensate of cigars had tumors.
- E. "Tar" from filter cigarettes is less hazardous than "tar" from the same cigaret without the filter. Hammond & Auerbach (unpublished, 1970) showed that in dogs exposed to smoke, equal amounts of particulates did not give equal numbers of lesions. Dogs exposed to filtered smoke had only half as many lesions (fibrosis, emphysema, total tumors) as dogs exposed to non-filtered smoke, even though dogs exposed to filtered smoke had twice as many cigarettes as the dogs exposed to non-filtered smoke.

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IV. What is the rationale for quoting nicotine numbers?

- A. Nicotine as a factor in smoking and disease was specifically exonerated in the Report of the Advisory Committee to the Surgeon General.
- B. Further arguments in favor of incriminating nicotine have been based on experiments of vague and questionable relevance based on mostly conjectural hypotheses.

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